Docket No. 33649-4

PATENT

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Bonnie L. Daee

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Patricia Ann Piers et al	:	Paper No.:
Serial No.:	10/768,755	:	Group Art Unit: 2873
Filing Date:	January 30, 2004	:	Examiner: Jessica T. Stultz

For: **Methods for Obtaining Ophthalmic Lenses Providing the Eye with Reduced Aberrations**

DECLARATION UNDER 37 C.F.R. 1.132

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Patricia Ann Piers declares that:

1. She is a co-inventor of and is familiar with the present U.S. patent application Serial No. 10/768,755 filed January 30, 2004 and entitled "Methods for Obtaining Ophthalmic Lenses Providing the Eye with Reduced Aberrations", and she is familiar with the Official Actions dated September 21, 2004 and May 11, 2005 issued by the Examiner in this patent application, and she is familiar with the Roffman et al U.S. Patent No. 6,554,425 cited in the Official Actions.

2. She received a degree of Master of Science in Physics and Vision Science from University of Waterloo in 1997, and has over 8 years of experience in the research and development of ophthalmic lenses and methods for ophthalmic correction. She is currently employed by the assignee of the present application, Advance Medical Optics, Inc. of Santa Ana,

California, as Director of Research. Prior to her current employment, she was employed by Pharmacia Groningen BV of Groningen, The Netherlands for 7 years as an Optical Scientist and Senior Scientist. She is named as inventor in four issued U.S. patents and as an inventor on additional pending U.S. applications.

3. The present invention is directed to an intraocular correction lens and methods for improving visual quality of an eye by implanting the inventive intraocular correction lens. The inventive intraocular correction lens has at least one aspheric surface and has aberrations. When the aberrations are expressed as a linear combination of polynomial terms, the lens is capable, in combination with a lens in the capsular bag of an eye, of reducing similar such aberration terms obtained in a wavefront having passed the cornea, thereby obtaining an eye sufficiently free from aberrations. In order for the inventive intraocular correction lens to be capable, in combination with a lens in a capsular bag of an eye, of reducing such aberration terms obtained in a wavefront having passed the cornea, to obtain an eye sufficiently free from aberrations, the aberrations resulting from optical irregularities in the corneal surfaces and the surfaces of the lens in the capsular bag of an eye must be determined. Thus, the inventive intraocular correction lens is configured based on such determinations.

4. For example, as described in the present application at page 4, beginning at line 10, the wavefront aberration of an uncorrected eye may be measured using a wavefront sensor, while the shape of at least one corneal surface in the eye is measured using a corneal topography. The at least one corneal surface and a lens located in the capsular bag of an eye comprising the cornea may then be characterized by a mathematical model, and by employing the mathematical model, the resulting aberrations of the corneal surface and the lens in the capsular bag may be calculated. More specifically, as described at page 5, beginning at line 30, aberration of the capsular bag lens may determined either by using the wavefront aberration values of the whole eye and from these subtracting the wavefront aberration values of the cornea, or, alternatively, by

modeling the optical system. In such modeling, a model of the cornea based on corneal measurements is used as a "starting point" capsular bag lens, the aberrations are calculated and the shape is modified until the calculated aberrations are sufficiently similar to the measured aberrations of the uncorrected eye.

5. Having reviewed the Roffman et al U.S. Patent No. 6,554,425 (Roffman et al), she finds no teaching or suggestion in this reference of the inventive intraocular correction lens or of a method of obtaining the inventive intraocular correction lens. Although Roffman et al disclose that "lens" means a spectacle lens, a contact lens, an intraocular lens, a corneal implant lens, an onlay lens and the like, or combinations thereof, she does not find a disclosure in Roffman et al of the present inventive intraocular corrective lens as described above. Specifically, she finds no teaching by Roffman et al of an intraocular lens having at least one aspheric surface which, when its aberrations are expressed as a lineal combination of polynomial terms, is capable of, in combination with a lens in the capsular bag of an eye, reducing similar such aberrations terms obtained in a wavefront having passed the cornea.

6. In her opinion, the Roffman et al teachings are deficient in that Roffman et al provide lenses which are designed based on measurements performed in front of the eye, and optionally employing corneal topography data. She finds no teaching or suggestion by Roffman et al for characterizing both the corneal surface and a lens located in the capsular bag as a mathematical model and employing the mathematical model to calculate the aberrations of the corneal surface and the lens in the capsular bag, and then using this information to provide a lens having at least one aspheric surface, which lens, when its aberrations are expressed as a linear combination of polynomial terms, is capable of reducing similar such aberration terms in a wavefront having passed the cornea, as in the inventive intraocular correction lens. One skilled in the art would, in her opinion, recognize that the external measurements and corneal topography upon which Roffman et al design their lenses is not equivalent to, and does not suggest, the

present intraocular correction lens which reduces aberration terms obtained in a wavefront having passed the cornea.

7. For example, Roffman et al disclose at column 1, beginning at line 57 that their lens is provided by measuring the basic refractive prescription of the lens wearer, measuring the wavefront aberrations of the lens wearer by providing visual targets and at least first and second distances, converting the aberration measurements to a height difference, and using the basic refractive prescription and converted difference to provide the lens. Roffman et al indicate that optionally corneal topographic data may be used, at column 2, line 45. Further, beginning at column 3, line 32, Roffman et al disclose that for lenses incorporating an inverse topographic elevation map of the lens wearer's cornea, the corneal topography may be determined and specifically for soft contact lens manufacture, the elevational data is applied to a lens model in an unflexed state and is transformed by taking into account the soft lens flexture, or wrap, when the lens is placed on the eye, and the data may be mapped onto a CNC grid pattern and used to make the lens or mold tool surface. While this disclosure is relevant to contact lens manufacture, in her opinion, it provides no teaching or suggestion to one of ordinary skill in the art regarding the design or manufacture of the inventive intraocular lens.

8. Finally, Roffman et al disclose at column 5, beginning at line 6, in the case of an intraocular lens, the corneal topography data may be combined with wavefront both on the lens front surface, back surface or a combination thereof, and the multiple focal portion may be placed, along with aberration correction, on the front or back surface, and finally, in all of the lenses, the distance, intermediate and narrow optical powers may be spherical or aspheric powers. This disclosure by Roffman et al does not, in her opinion, teach or suggest to one of ordinary skill in the art, the present inventive intraocular correction lens, or the method of designing such a lens.

9. It is therefore her opinion that Roffman et al do not teach or suggest the inventive intraocular correction lens or teach one of ordinary skill in the ophthalmic art to how to design the inventive intraocular correction lens.

10. She hereby declares that all statements made herein are of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued hereon.

Respectfully submitted

Patricia Ann Piers

29-07-2005

Date

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